DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 13 2012

Re: EXPAREL
Docket No. FDA-2012-E-0491

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is concerning the application for patent term extension for U.S. Patent No. 6,132,766 filed by Pacira Pharmaceuticals, Inc., under 35 U.S.C. 156. The human drug product claimed by the patent is EXPAREL (bupivacaine), which was assigned new drug application (NDA) No. 22-496.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). However, our records also indicate that EXPAREL (bupivacaine) does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1). The active ingredient in EXPAREL (bupivacaine) is the base of an active ingredient that has been previously approved for commercial marketing or use in many other new drug applications, including Marcaine Hydrochloride injection by Hospira, Sensorcaine injection by APP Pharmaceuticals, and Bupivacaine Hydrochloride preservative-free injection by International Medication Systems Ltd., and others.

The NDA was approved on October 28, 2011, which makes the submission of the patent term extension application on December 22, 2011, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Mallary K. de Merlier
KNOBBE, MARTENS, OLSON & BEAR, LLP
12790 El Camino Real
San Diego, CA 92130